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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/700,368

11/03/2003

Joseph M. Pastore

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

05/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/700,368	Applicant(s) PASTORE ET AL.	
	Examiner Christopher A. Flory	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 13 November 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: simultaneous delivery of all three of atrial pacing, multi-site ventricular pacing, and parasympathetic stimulation for reducing ventricular wall stress. While each is disclosed in a potentially individual manner, no disclosure of *simultaneous* delivery is made, and the limitation of *simultaneous* delivery must be cancelled.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1 and 11 require that atrial and multi-site ventricular pacing be delivered simultaneously with parasympathetic stimulation for reducing ventricular wall

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stress. While the disclosure does enable simultaneous ventricular pacing and parasympathetic stimulation, it does not address the addition of atrial pacing stimulation simultaneously or in conjunction with the other two therapy modalities.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, 5, 7, 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al. (U.S. 2003/0229380).

In regards to claim 1, Adams et al. discloses an implantable device and method for delivering cardiac function therapy to a patient with multiple electrodes (see for example paragraphs 2, 9 and 12), in which includes and an embodiment comprising a biventricular pacing system (see for example paragraph 55), which is interpreted by Examiner to inherently include multiple pacing channels since the system comprises pacing at multiple sites. Adams et al. also discloses that the device comprises a parasympathetic stimulation system (see for example paragraph 11), which Examiner interprets as including a parasympathetic stimulation channel.

Further regarding claim 1, in the same field of endeavor, Lovett et al. (US 2002/0091415) discloses that ventricular wall stress and heart rate share an inverse relation, in that an increase of heart rate causes a decrease in pulse pressure and concomitantly a decrease in wall stress (paragraph [72]). Therefore, a therapy modality as described in Adams et al. which increases heart rate (ABSTRACT; paragraphs [5], [6]) also inherently decreases wall stress. Alternatively, Adams et al. teaches of a controller for controlling the delivery of pacing pulses to pacing sites (see for example paragraph 10), in which the controller can deliver pacing therapy in conjunction with parasympathetic stimulation (see for example paragraph 11), which Examiner interprets to be capable of reducing ventricular wall stress given that the Adams et al. device meets all the structural limitations set forth in the instant claims.

Still further regarding claim 1, Adams et al. is held to disclose a device capable of delivering stimulation simultaneously, as it meets all of the structural limitations set forth in the claims of the instant application.

In regards to claim 2, Adams et al. discloses a sensor for measuring cardiac output (see for example paragraphs 10 and 92), wherein the controller is programmed to modulate the delivery of parasympathetic stimulation in accordance with the measured output (see for example paragraphs 11, 42 and 46).

In regards to claim 4, Adams et al. discloses slowing the heart rate of a patient by parasympathetic stimulation (see for example paragraphs 38 and 39).

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In regards to claims 5, 7 and 8, Adams et al. discloses monitoring a patient's blood pressure, and the use of an activity sensor for monitoring a patient's exertion level (see for example paragraphs 46, 55 and 64).

5. Claims 1, 2, 4, 5, 7, 8, 10-12, 14, 15, 17, 18 and 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Casavant et al. (US 2004/0088015).

Applicant is directed particularly to paragraphs [35], [36], [60] and [71], as well as Figs. 3-5.

6. Claims 1-3, 5, 7, 8, 10-13, 15, 17, 18 and 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Shafer et al. (US 2004/0172075).

Applicant is directed particularly to paragraphs [23], [27], [28], [41] and [46], as well as Figure 5.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 11, 12, 14, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. 2003/0229380).

In regards to claim 11, Adams et al. discloses an implantable device and method for delivering cardiac function therapy to a patient with multiple electrodes (see for

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example paragraphs 2, 9 and 12), in which includes and an embodiment comprising a biventricular pacing system (see for example paragraph 55), which is interpreted by Examiner to inherently include multiple pacing channels since the system comprises pacing at multiple sites. Adams et al. also discloses that the device comprises a parasympathetic stimulation system (see for example paragraph 11), which Examiner interprets as including a parasympathetic stimulation channel.

Further regarding claim 11, in the same field of endeavor, Lovett et al. (US 2002/0091415) discloses that ventricular wall stress and heart rate share an inverse relation, in that an increase of heart rate causes a decrease in pulse pressure and concomitantly a decrease in wall stress (paragraph [72]). Therefore, a therapy modality as described in Adams et al. which increases heart rate (ABSTRACT; paragraphs [5], [6]) also inherently decreases wall stress. Alternatively, Adams et al. teaches of a controller for controlling the delivery of pacing pulses to pacing sites (see for example paragraph 10), in which the controller can deliver pacing therapy in conjunction with parasympathetic stimulation (see for example paragraph 11), which Examiner interprets to be capable of reducing ventricular wall stress given that the Adams et al. device meets all the structural limitations set forth in the instant claims.

Still further regarding claim 11, Adams et al. does not expressly disclose that the pacing is delivered simultaneously with the parasympathetic nerve stimulation. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to delivery the therapies in a synchronous manner, since synchronous pacing

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therapy as well as synchronous pacing and nerve stimulating therapies are well known in the implantable stimulator art.

In regards to claim 12, Adams et al. discloses a sensor for measuring cardiac output (see for example paragraphs 10 and 92), wherein the controller is programmed to modulate the delivery of parasympathetic stimulation in accordance with the measured output (see for example paragraphs 11, 42 and 46).

In regards to claim 14, Adams et al. discloses slowing the heart rate of a patient by parasympathetic stimulation (see for example paragraphs 38 and 39).

In regards to claims 15, 17 and 18, Adams et al. discloses monitoring a patient's blood pressure, and the use of an activity sensor for monitoring a patient's exertion level (see for example paragraphs 46, 55 and 64).

9. Claims 3, 6, 9, 10, 13, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. 2003/0229380).

In regards to claims 3 and 13, although Adams et al. teaches of the use of a sensor/circuit for measuring impedance to detect cardiac output (see for example paragraph 46), Adams et al. does not specifically teach of the use a trans-thoracic impedance measuring sensor/circuit. Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Adams et al. to include a trans-thoracic impedance to measure cardiac output, since this type of impedance sensor/circuit is well known in the art as a efficient and effective detector of cardiac output.

In regards to claims 6 and 16, Adams et al. teaches of the system providing parasympathetic stimulation when the activity level is below a particular value (see for example paragraph 46). Although Adams et al. does not specifically state that parasympathetic stimulation only when the measured activity level is below a particular value, Examiner takes the position that such a requirement would have been an obvious modification to one having ordinary skill in the art at the time of the invention since Adams et al. teaches that it is desirable to induce parasympathetic stimulation to reduce a patient's heart rate (see for example paragraph 11) when the activity level is stabilized (see for example paragraph 46), in order to provide effective and efficient parasympathetic stimulation.

In regards to claims 9, 10, 19 and 20, (see for example paragraphs 46 and 92), Adams et al. does not specifically state the use of a minute ventilation sensor or an accelerometer, for an exertion level sensor; however, Adams et al. does teach that the activity sensor can be one of a multiple types of exertion/metabolic level sensors (see for example paragraph 64). Thus, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Adams et al. to include a minute ventilation sensor or accelerometer, since these are commonly known activity/exertion sensors that can be used to efficiently and effectively measure a patient's metabolic demand.

Response to Arguments

10. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

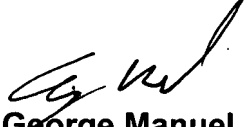
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory
16 April 2007


George Manuel
Primary Examiner